



The United States Department of Justice

Drug Enforcement Administration



*Controlled Substance and
Legend Drug Diversion;
A Law Enforcement and Regulatory Perspective*

Virginia Pharmacy Diversion Awareness Conference
National Association of Boards of Pharmacy (NABP)
Virginia Board of Pharmacy
Drug Enforcement Administration

Sheraton Hotel
Norfolk, Virginia
May 30/31, 2015

PLAINTIFFS TRIAL
EXHIBIT
P-15962-A

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Disclosure Statement

I have no financial relationships to disclose
and

I will not discuss off-label use and/or
investigational drug use in my presentation

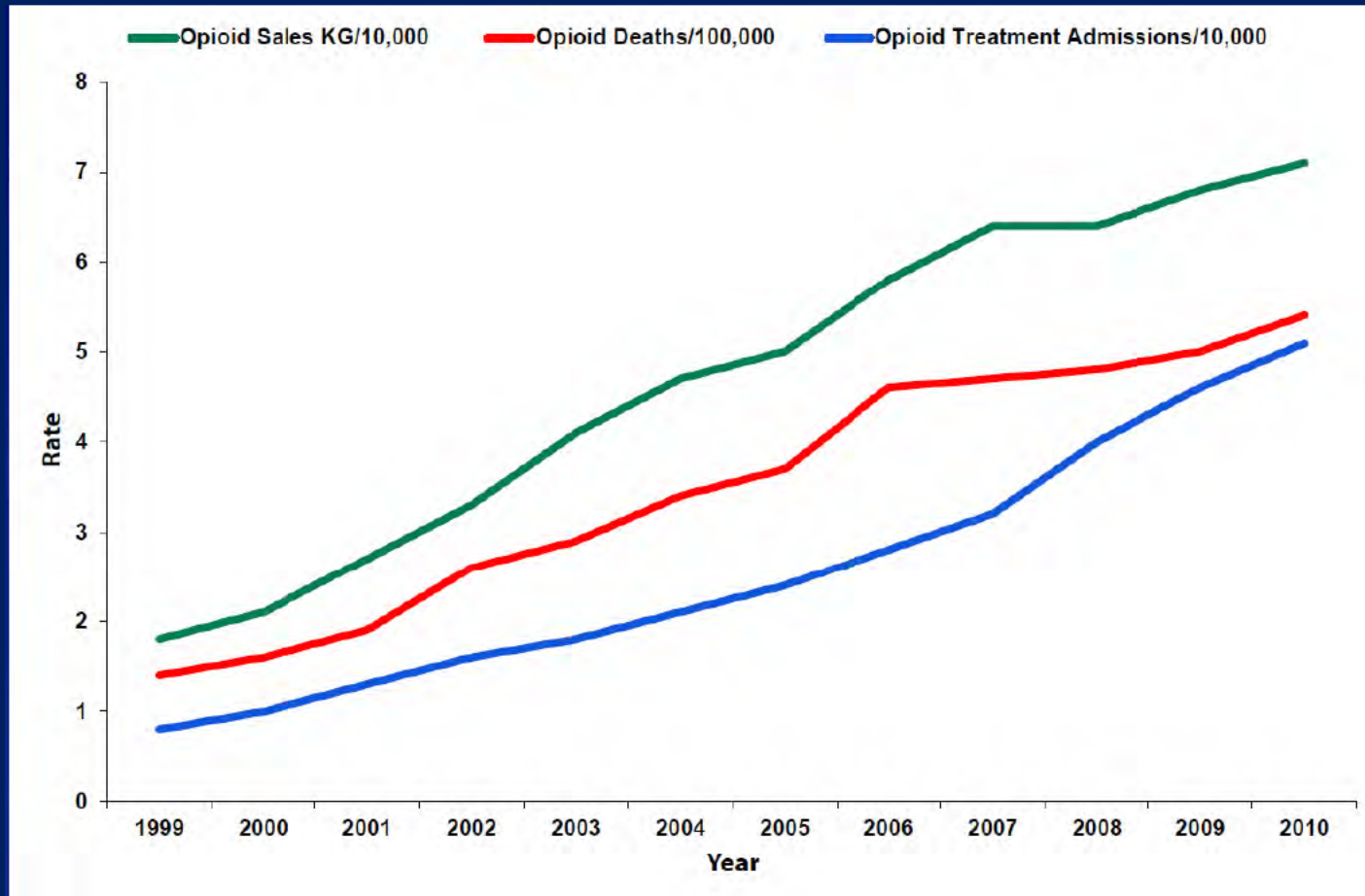


Goals and Objectives

- Background of prescription drug and opioid use and abuse – scope of the problem and potential solutions
- Identify and discuss the pharmacology of commonly diverted and abused pharmaceuticals
- Identify methods of pharmaceutical diversion and discuss how the pharmacist can prevent diversion in the retail setting
- Discuss the pharmacist and corresponding responsibility
- Discuss disposal regulations



U.S. Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, 1999-2010

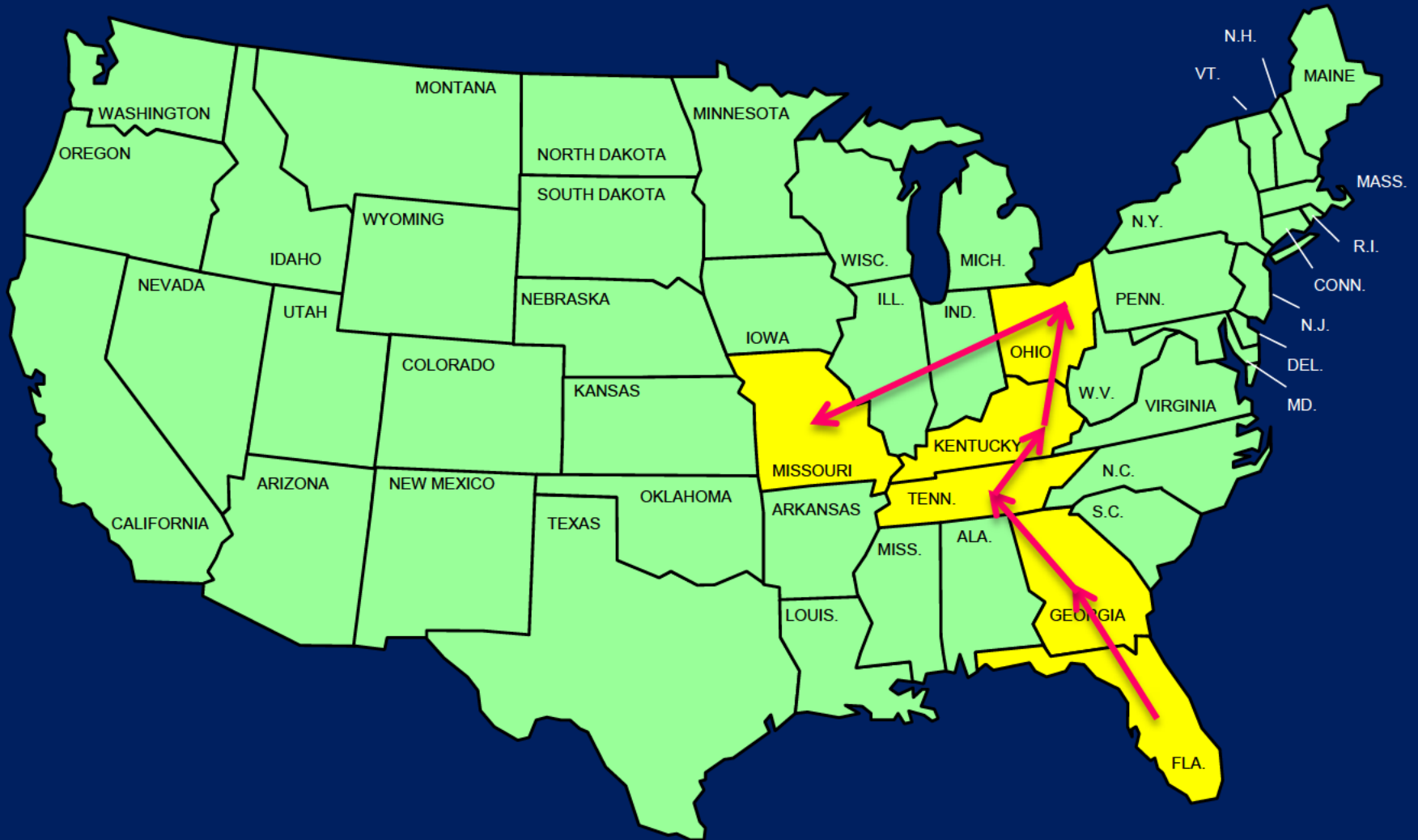


Source: National Vital Statistics System (NVSS),
DEA's Automation of Reports and
Consolidated Orders System, SAMHSA's
Treatment Episode Data Set

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MIGRATION OF PAIN CLINICS



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‘The Florida Migration’

➤ Vast majority of ‘patients’ visiting Florida “pain clinics” come from out-of-state:

- Georgia
- Kentucky
- Tennessee
- Ohio
- Massachusetts
- New Jersey
- North and South Carolina
- Virginia
- West Virginia



Checks and Balances of the CSA and the Regulatory Scheme

➤ Distributors of controlled substances

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” (21 CFR § 1301.74)



Pharmacists have a responsibility to protect patients, as well as the public, from the abuse, misuse and diversion of prescription drugs.

2014 AACP Program Material



Checks and Balances Under the CSA

Pharmacists – The Last Line of Defense

“The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”

(21 CFR § 1306.04(a))

U.S. v. Hayes 595 F. 2d 258 (5th Cir 1979)

U.S. v. Leal 75 F. 3d 219 (6th Cir 1996)

U.S. v. Birbragher 603 F. 3d 478 (8th Cir 2010)

East Main Street Pharmacy 75 Fed. Reg. 66149 (Oct. 27, 2010)



Potential Red Flags

Many customers receiving the same combination of prescriptions; cocktail

Many customers receiving the same strength of controlled substances; no individualized dosing: multiple prescriptions for the strongest dose

Many customers paying cash for their prescriptions

Early refills

Many customers with the same diagnosis codes written on their prescriptions;

Individuals driving long distances to visit physicians and/or to fill prescriptions;



Potential Red Flags continued

Customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and

Customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).

Overwhelming proportion of prescriptions filled by pharmacy are controlled substances

Pharmacist did not reach out to other pharmacists to determine why they were not filling a particular doctor's prescription

Verification of legitimacy not satisfied by a call to the doctors office



Red Flag?

What happens next?

You attempt to resolve...



Resolution is comprised of many factors

- Verification of a valid practitioner DEA number is required! It is not, however, the end of the pharmacist's duty. Invalid DEA number = Invalid RX
- Resolution cannot be based solely on patient ID and prescriber verification.
- You must use your professional judgment, training and experience...we all make mistakes
- Knowledge and history with the patient
- Circumstances of prescription presentation
- Experience with the prescribing practitioner
- It does not require a call to the practitioner for every CS RX
- This is not an all-inclusive list...



Who do I call to report a practitioner?

- State Board of Pharmacy/Medicine/Nursing/Dental
- State/County/Local Police
- DEA local office and Tactical Diversion Squad
- Health department
- HHS OIG if Medicare/Medicaid fraud